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## EUROPEAN PATENT APPLICATION

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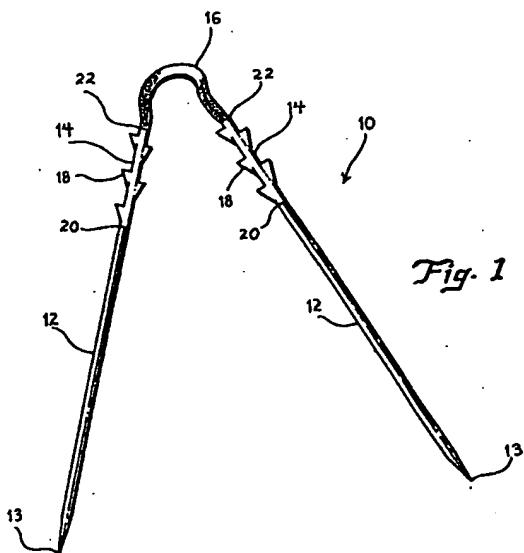
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### ④ Device and method for repairing torn tissue.

⑤ A device 10 for repairing torn tissue or muscle such as the meniscus 44,45 of the knee. The device consists of a pair of needles 12 detachably secured to a pair of anchoring members 14 having a plurality of barb-like projections 18 extending outwardly therefrom. The anchoring members are joined by a suture 16 which connects the ends of the anchoring members opposite the needles.



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**BACKGROUND OF THE INVENTION****1. Field Of The Invention**

The present invention relates to a device for repairing torn tissue and muscle in the body, and more particularly to a device for repairing a torn meniscus in the human knee. A method of repairing torn meniscal tissue is also disclosed.

**2. Discussion Of The Prior Art**

The surgical repair of torn tissue and muscles in the body has typically been performed through incisions in the body to expose the area under repair and the actual procedure includes the provision of sutures, staples or fasteners. The advent of arthroscopic techniques and endoscopic equipment have reduced the size and depth of the incision required to perform the repair procedure; however, the use of conventional devices in many cases requires a highly skilled surgeon to perform the repair, and usually requires complete immobilization of the surgical area following the repair procedure.

Surgical repair of cartilage and muscle in joints such as the knee often requires extraordinary skill on the part of the surgeon to reduce damage to adjacent nerves, blood vessels, muscles and tendons in the knee joint. In particular, surgical repair of the fibrocartilage disks within the knee known as the menisci, which are attached peripherally to the joint capsule, requires precision to avoid such damage.

In the past, meniscal surgery has included procedures for partial to complete removal of a torn meniscus, as well as attempts to surgically suture or staple the tear in the meniscus to allow for healing. Other techniques have included removal of portions of the meniscus to arrest the spread of the tear.

A technique has been developed using arthroscopic instruments which provides for meniscal repair through the use of a pair of surgical needles which are inserted through cannuli into the knee on opposite sides of the tear in the meniscus to be repaired. The needles are linked by a single suture which is pushed down through the cannuli and across the tear. An incision is made in the skin at the point where the needles exit the knee joint so that the leading end of each needle may be grasped and pulled through the joint. The ends of the sutures are then grasped after the needles are removed from the suture ends and the suture is then tied outside the skin so that a horizontal suture is created in the meniscus. This procedure is repeated for placement of as many sutures as necessary to repair the meniscus tear. This pro-

cess is very time consuming, and the strength of the repair is dependent upon the tension created by the knot tied in the suture.

The need exists for a device for repairing torn tissue, such as the meniscus of the knee, which obviates the disadvantages encountered in the prior art and provides an efficient, suture-type device which expedites the surgical procedure and reduces the amount of precision necessary on the part of the surgeon during the procedure.

**SUMMARY OF THE INVENTION**

The present invention provides a novel device for repairing torn tissue and muscle such as the menisci in the knee joint which expedites the surgical process and facilitates complete healing of the tear. The device of the present invention reduces the precision required on the part of the surgeon to accurately place and secure the suture at the tear site, and expedites the surgical process by eliminating the requirement of securing the ends of the sutures together to stitch the tear. The device of the present invention allows a surgeon to reduce the trauma to the surrounding tissue and facilitates healing of the torn muscle tissue by providing a completely resorbable suture-like device which may be accurately placed across the tear and which may remain in place until the tear is completely healed.

The device for repairing torn tissue and muscles of the present invention comprises a pair of surgical needles each secured at one end to a pair of anchoring members which essentially comprise absorbable rods having outwardly projecting barbs. Each anchoring member is secured at a second end to an absorbable flexible material such as a suture which extends between the two anchoring members. The means of securement between the needles and anchoring members, and between the anchoring members and the suture may include adhesives, swaging, crimping or a quick-release connection such as heat-shrinkable tubing. Preferably, the suture and the anchoring members are constructed of a bioresorbable material.

The barbs of the anchoring member have a tapered configuration towards the needles so that as the needles are pushed through the tissue, the barbs easily pass through the tissue with the needle. The configuration of the barbs is such that the anchoring members pass easily through the tissue in the forward direction, but are prevented from moving in the reverse direction. The barbs are provided to anchor the device in the tissue.

The needles of the present invention may be straight needles, preferably constructed of stainless steel or other surgical grade metal alloy. Although preferably straight, it is contemplated that the nee-

dies may be curved, similar to suture-type needles.

In use, the damaged or torn meniscus in the knee is arthroscopically approached from the front of the knee by inserting the needles across the tear and then advancing the needles through the meniscus across the tear, drawing the absorbable anchoring means through the meniscus and then through the joint capsule to exit through a previously made incision. The suture is then pulled substantially flush with the meniscus across the tear, whereby the surgeon may then pull the needles through the incision, which had been made to expose the outer surface of the joint capsule. The needles are then cut, or may be detached by a sharp pull when the suture contacts the meniscus across the tear. The barbed anchoring means are then cut substantially flush with the joint capsule on the side opposite the suture, the incision is closed; and the anchoring means holds the suture in place. The barbs on the anchoring means serve to maintain the position of the device within the meniscus, and the suture and anchoring means serve to maintain the tear at close approximation to enhance healing. The material compositions of the suture and the anchoring means are selected to provide the desired resorption rate to allow sufficient time for healing.

In the event that the tissue being repaired is not sufficiently strong to retain the barb members in place, a retaining flange may be utilized which is slipped over the barbs after it is drawn through the tissue to apply counter pressure against the surface of the joint capsule to pull the suture tight across the tear.

#### BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing features of the present invention will become more readily apparent and may be understood by referring to the following detailed description of an illustrative embodiment of the device for repairing torn tissue and muscle, taken in conjunction with the accompanying drawings, in which:

Fig. 1 illustrates a perspective view of the device of the present invention;

Fig. 2 illustrates a perspective view of an alternate embodiment of the device of the present invention;

Fig. 3 illustrates a perspective posterior view of the muscular structure of the knee;

Fig. 4 illustrates a cut-away perspective view of the knee of Fig. 3 along line 4-4 showing the device of the present invention in position during the meniscal repair procedure;

Fig. 5 illustrates a perspective anterior view of the knee of Fig. 3 with the device of the present invention in position during the meniscal repair

procedure;

Fig. 6 illustrates a perspective view of an alternate embodiment of the device of Fig. 1; and Fig. 7 illustrates a perspective view of a further alternate embodiment of the device of Fig. 1.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now in specific detail to the drawings, in which like reference numerals identify similar or identical elements throughout the several views, Fig. 1 shows the repair device 10 of the present invention. Repair device 10 generally comprises a pair of metal needles 12, preferably constructed of stainless steel or other surgical metal alloy, having a sharp tip 13 at one end to facilitate penetration through tissue, and a blunt end at the other end. In a preferred embodiment, the length of each needle is between 6 inches and 10 inches. However, this is not intended to be limiting as clearly needles of various lengths may be utilized.

Secured to needles 12 are a pair of anchoring members 14 which are constructed of a bioresorbable material, such as homopolymers and copolymers of lactide, glycolide, polydioxanone, trimethylene carbonate, polyethylene oxide or other bioabsorbable materials or blends of these copolymers. Preferably, the anchoring members 14 are formed of a copolymer of lactide and glycolide. Anchor members 14 are linked by a flexible material 16 such as a suture, also constructed of a bioresorbable material, such as a lactide/glycolide copolymer. Flexible material 16 allows for movement of anchoring members 14 with respect to one another. Anchor members 14 preferably have a length of between about 1 inch and 2 inches.

Needles 12 are secured to anchor members 14 as indicated at joint 20, and the anchor members 14 are secured to suture 16 as at joint 22. The anchor members 14 of device 10 may be secured to the needles 12 by means of adhesives, crimping, swaging or the like, and joint 20 may be formed by heat-shrinkable tubing. It is preferred that joint 20 is a detachable connection, such that needle 12 may be removed from anchor member 14 by a sharp tug or pull or by cutting as described below. Anchor members 14 are secured to suture 16 preferably by inset molding.

Anchor members 14 are provided with a plurality of barb-like projections 18 which serve to anchor device 10 in the tissue to be repaired. Barbs 18 have a tapered shape to allow the anchor members 14 to be pushed through tissue or muscle, such as the menisci of the knee, in a first forward direction and to prevent the anchor members from traveling in a reverse direction. Although as shown in Fig. 1 five barbs 18 are provided, any number

may be provided, so long as the barbs penetrate the tissue to anchor the device 10.

Fig. 2 illustrates an alternate embodiment of the device of the Fig. 1. Device 30 is similar in construction to device 10 except that curved needles 32 are provided. Needles 32 are secured to anchoring members 14 as described above, which are provided with a plurality of barbs 18 which taper in the direction of needles 32 to facilitate insertion of the device into tissue. Anchor members 14 are connected through suture 16 as described above. The remaining elements of device 30 are identical to those of device 10 as illustrated in Fig. 1.

Fig. 3 illustrates the muscular and ligament structure of the knee 34, including the pertinent components of the knee to which the present invention is directed. As is well known, the femur 35 is joined to tibia 36 and fibula 37 by muscles, tendons and ligaments, and these bones are separated and cushioned by the medial meniscus 44 and lateral meniscus 45. Condyles 38 of femur 35 rest on the menisci, and the bones are joined and supported by anterior cruciate ligament 39, ligament of Wrisberg 40, posterior cruciate ligament 41, and transverse ligament 46 (see Fig. 5). The joint capsule is formed by tibial collateral ligament 42 and fibular collateral ligament 43.

Fig. 4 illustrates the device 10 of the present invention in use, showing knee 34 along lines 4-4 of Fig. 3. The lateral meniscus 45 of a knee 34 having a tear 52 is repaired with the present invention by forcing needles 12 through the meniscus on one side of the tear, through the torn region, and out the meniscus tissue on the opposite side of the tear on the outside of the knee. The device is fully inserted so that flexible member 16 becomes substantially flush with meniscus 45 and is pulled taut. Barbs 18 of anchor members 14 anchor the device in the meniscus 45 and prevent the device from backing off, so that tear 52 is maintained in an abutting relationship across itself to facilitate healing. Needles 12 may then be removed from anchoring members 14 by means of a sharp yank or tug, or are cut as they are accessed from the opposite side of the knee by a suitable incision. Anchoring members 14 are then trimmed so as to be flush with the surface of meniscus 45 or the joint capsule. The material of which anchor members 14 and suture 16 are constructed are preferably bio-resorbable materials which resorb at a rate which is slow enough to facilitate healing of the tear in the tissue.

During arthroscopic surgery, as best seen in Fig. 5, the surgeon will approach the torn meniscus from in front of the knee and insert the two needles 12 into the meniscus 44 or 45. As the needles 12 are pushed through the meniscus 45 to draw the

edges of the tear together, the surgeon will make an incision on the opposite side of the knee adjacent the needles to avoid pushing the needles through the skin. As the needles are withdrawn, the suture 16 is pulled tight to hold the edges of the tear together while the barbs 18 prevent the backing off of the device 10 through the tissue. The needles are then removed, and the anchor members are trimmed to the surface level of the joint capsule and the incisions are stitched.

Turning now to Fig. 6, there is shown a further embodiment of the device of the present invention. Device 60 is identical to device 10 except for the provision of retaining flanges 62 which slip over needles 12 and anchoring members 14 to apply counter pressure against the surface of the joint capsule to pull the suture 16 tight across the tear in the meniscus. Flanges 62 are utilized when the strength of the tissue through which the device passes is insufficient to hold barbs 18 in place.

Figure 7 illustrates a further embodiment of the device of the present invention. Device 70 is identical to device 10 except that barbs 18 are aligned with each other, rather than staggered as in accordance with Figure 1. Clearly, device 70 may include curved needles as shown in Fig. 2 or retaining flanges 62 as shown in Fig. 6.

#### Claims

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1. A tissue tear repair device comprising:

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at least one tissue piercing member, a tissue connecting member provided for each tissue piercing member and attached to each repetitive tissue piercing member, each tissue connecting member having anchoring means for securing each said tissue connecting member in said tissue, said tissue connecting member attached to a flexible material.

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2. A device according to claim 1, and comprising:
  - a pair of tissue piercing members, and
  - a pair of tissue connecting members, said members having anchoring means for securing said members in said tissue, said members being joined by flexible material,

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wherein each of said tissue connecting members are secured to one of said tissue piercing members.

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3. A device according to claim 2, further comprising at least one retaining flange member which fits over said tissue piercing members and tissue connecting members.

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4. A device according to claim 2 or 3, wherein said tissue piercing members comprise a pair

of straight surgical needles, each of said needles being secured to a respective one of said tissue connecting members.

5. A device according to claim 2 or 3, wherein said tissue piercing members comprise a pair of curved surgical needles, each of said needles being secured to a respective one of said tissue connecting members.

10. A device according to any one of the preceding claims, wherein said tissue connecting members comprise resorbable material.

15. A device according to any one of the preceding claims, wherein said anchoring means of said tissue connecting members comprises a plurality of barb-like members which hold the tissue connecting members in place across a tear in tissue.

20. A device according to claim 7, wherein said barb-like members have a tapered shape to permit penetration through tissue in a forward direction but prevent movement in a reverse direction.

25. A device according to any one of the preceding claims, wherein said tissue connecting members are secured to said tissue piercing means by adhesives, swaging or crimping.

30. A device according to any one of claims 1 to 7, wherein said tissue connecting members are secured to said tissue piercing means by heat-shrinkable tubing.

35. A device according to any one of the preceding claims, wherein said flexible material comprises a resorbable suture.

40. A device according to any one of the preceding claims for repairing the meniscus of a knee, comprising:

45. a pair of tissue piercing members each having a pointed end and a blunt end,

50. a pair of tissue anchoring members each having a plurality of barb-like projections extending outwardly from said members, each said anchoring member being secured at a first end to said blunt end of one of said piercing members, and

55. a linking member for joining said anchoring members together, said linking member joining an end of each anchoring member at a second end.

13. A device according to claim 12, wherein said tissue piercing members comprise surgical needles detachably secured to said anchoring members.

14. A device according to claim 12 or 13, wherein said linking member comprises a suture.

15. A device according to any one of the preceding claims, for repairing torn meniscal tissue comprising:

16. A device according to claim 1, for repairing torn meniscal tissue comprising:

17. A device according to claim 16, wherein said first and second anchoring members are provided with a plurality of outwardly projecting barbs for grasping tissue.

18. A device according to any one of the preceding claims, for repairing torn tissue, in particular the meniscus of a knee, comprising:

19. A device according to any one of the preceding claims, comprising a pair of tissue piercing

members and a pair of tissue connecting members, said connecting members having anchoring means for securing said members in said tissue, said connecting members being joined by flexible material, each of said tissue piercing members respectively extending from a distal end of each of said tissue connecting members.

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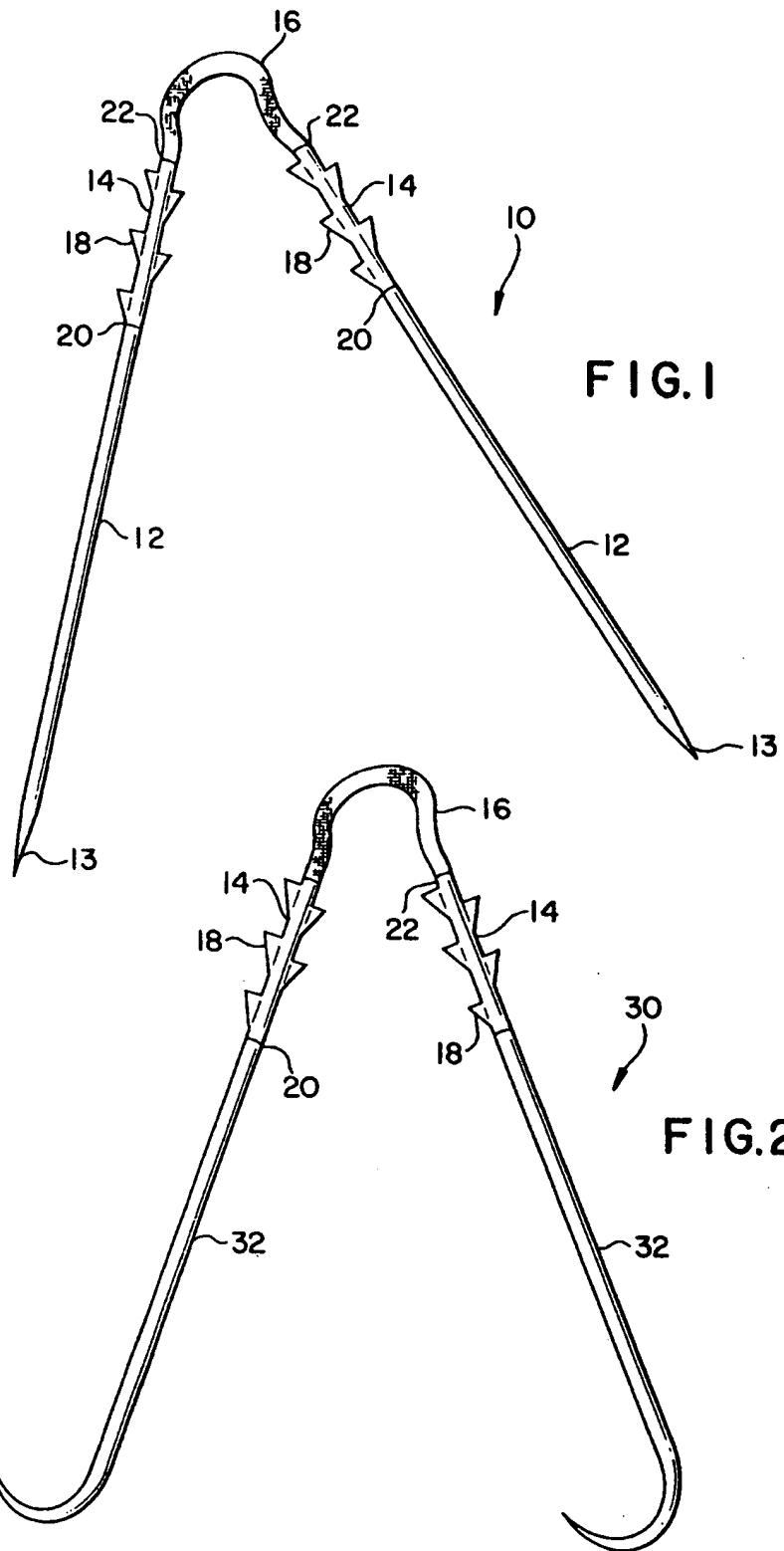
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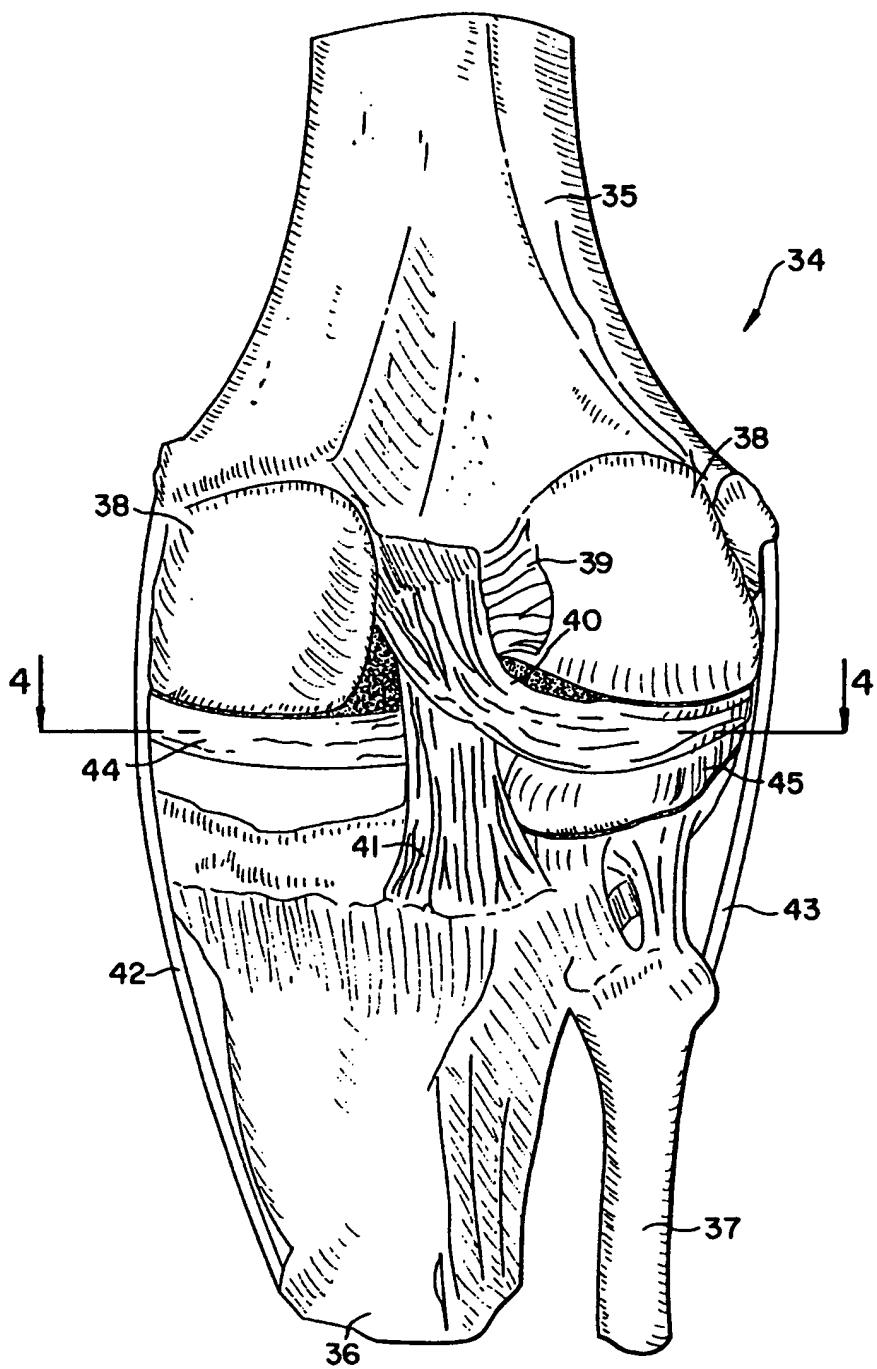


FIG.3

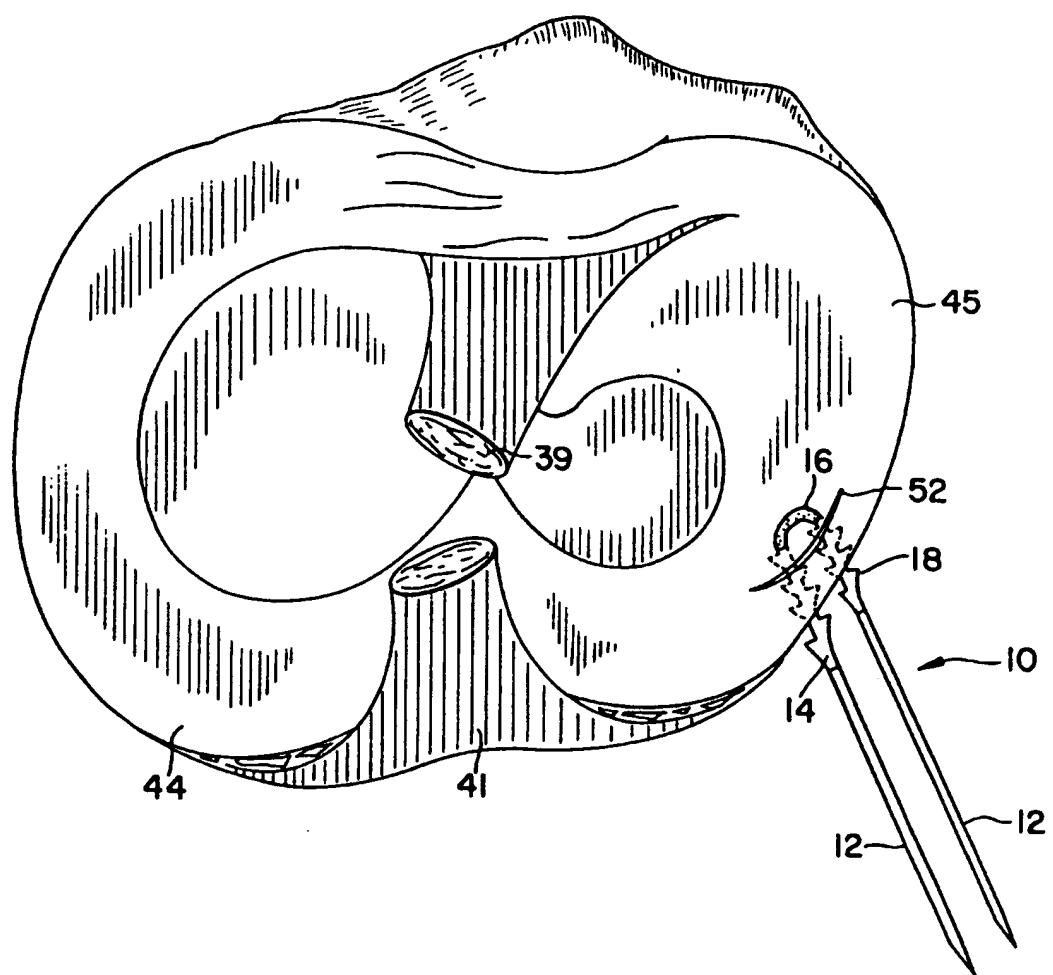


FIG.4

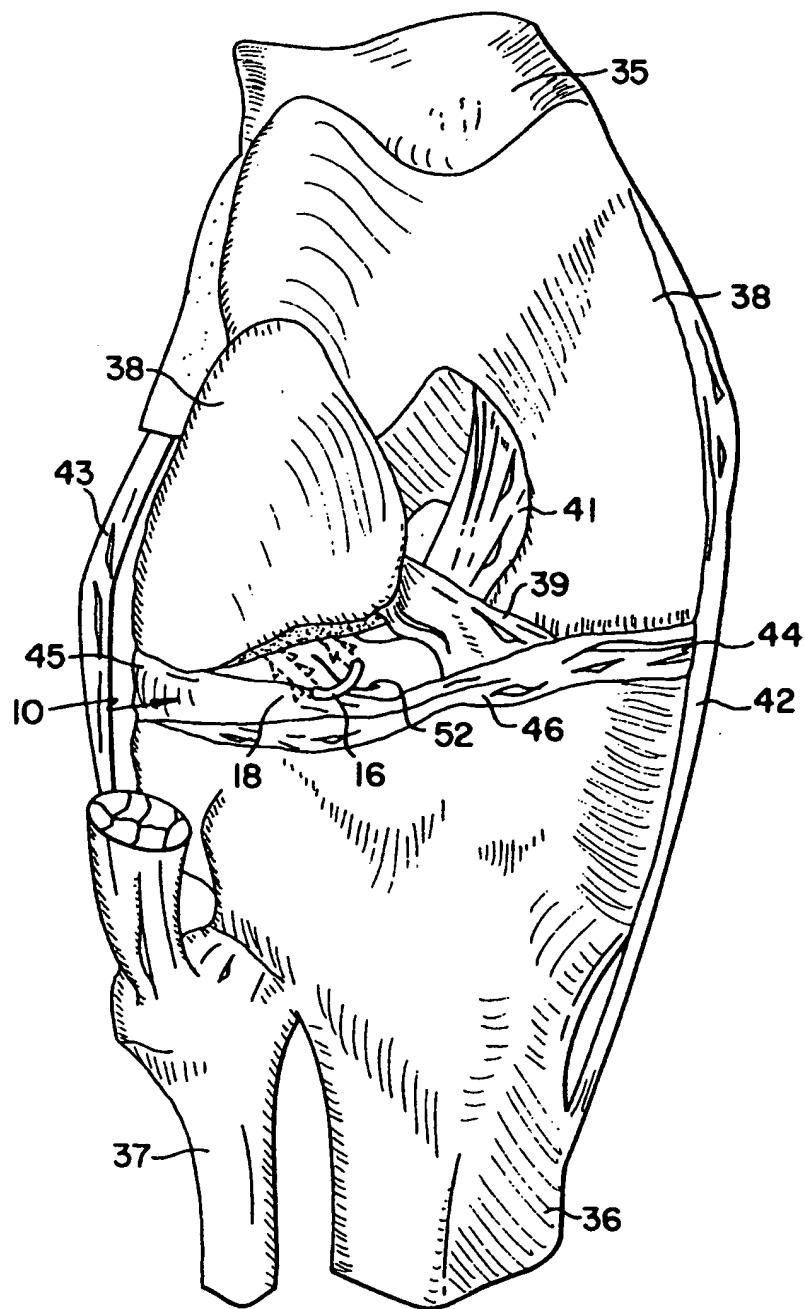


FIG.5

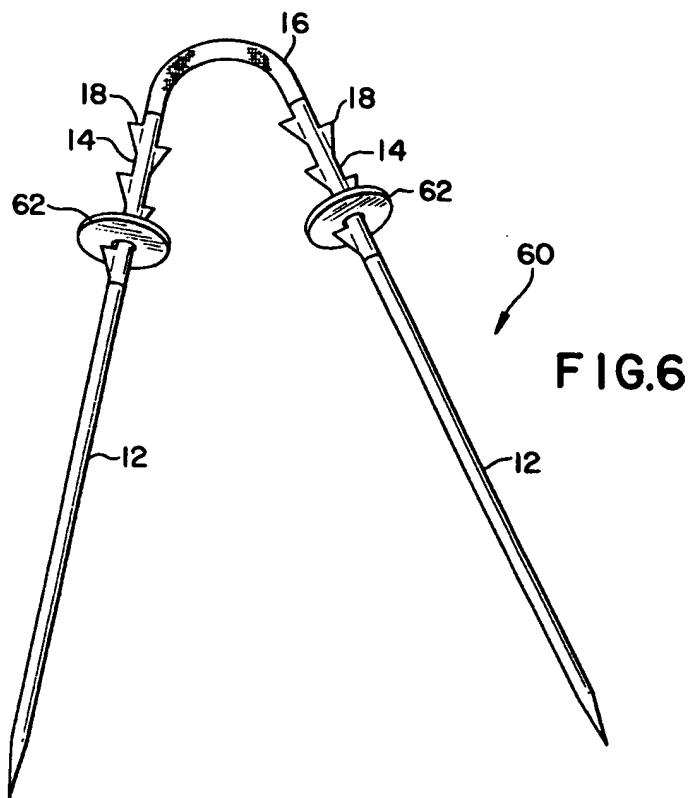


FIG.6

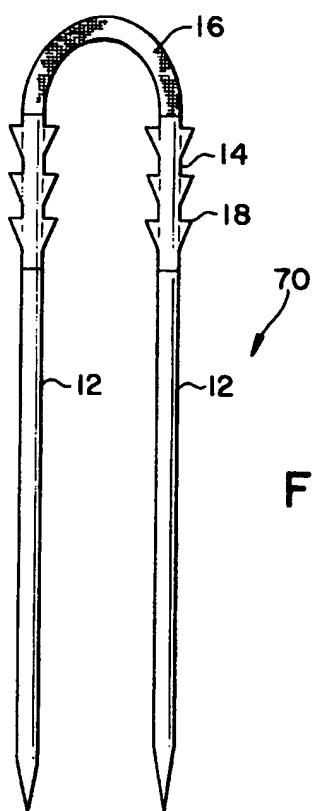


FIG.7



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EUROPEAN SEARCH REPORT

Application Number

EP 92 10 7986

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. CL.5)
			TECHNICAL FIELDS SEARCHED (Int. CL.5)
X	US-A-4 997 436 (OBERLANDER)	1,2,5-8, 11,12, 14-17,19	A61B17/06 A61B17/064
Y	* abstract; figures 1,2 *	3,4,9, 13,15,18	
	* column 1, line 15 - line 18 *		
	* column 4, line 7 - line 24 *		
Y	WO-A-8 701 270 (ACUFEX MICROSURGICAL INC.) * abstract; figures 8,9 *	3,18	
	* page 11, line 31 - page 12, line 13 *		
Y	US-A-4 858 603 (CLEMOW ET AL.) * abstract; figures *	4,9,13, 15	
	* column 2, line 8 - line 13 *		
A	US-A-4 741 330 (HAYHURST) * abstract; figures *	1	
A	US-A-3 570 497 (LEMOLE) * abstract; figures *	1	TECHNICAL FIELDS SEARCHED (Int. CL.5)
A	EP-A-0 390 613 (UNITED STATES SURGICAL CORPORATION) * abstract; figures 1A-1E *	1	A61B A61F
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The present search report has been drawn up for all claims			
Place of search THE HAGUE	Date of completion of the search 21 AUGUST 1992	Examiner ZEINSTRA H.	
CATEGORY OF CITED DOCUMENTS		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons A : member of the same patent family, corresponding document	
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document			